Citation:

Felkner M, Suarez L, Hendricks K, Gunter EW. Blood folate levels on the Texas-Mexico border. *Tex Med*. 2002; 98 (11): 58-60.

PubMed ID: 12448957

Study Design:

Cross-sectional study

Class:

D - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine whether there was an increase in folate levels specifically among the Mexican-American population along the Texas-Mexico border, since folic acid fortification of enriched grain products in 1998.

Inclusion Criteria:

- Women who gave birth to live-born infants without apparent or prenatally diagnosed congenital anomalies that required medical intervention
- Resident women who delivered in a hospital or birthing center in the 14 Texas-Mexico border counties.

Exclusion Criteria:

Samples from 1995 and 2000: Excluded because the sample numbers from these two years were too small to make statistically valid comparison.

Description of Study Protocol:

- *Recruitment:*
  - Randomly selected women who delivered in a hospital or birthing center in 14 border counties of Texas-Mexico
  - They were controls in a population-based case-control neural tube defect (NTD) study, from 1995 through 2000
- *Design:* Cross-sectional study
- *Dietary intake/Dietary assessment methodology:* Not applicable
- *Blinding used:* Outcome variables were analyzed using objective methods
- *Intervention:* Folic acid fortification policy

- *Statistical analysis:* Sample means were calculated for each year (1996, 1997, 1998 and 1999).

Data Collection Summary:

- *Timing of measurements:* From 1995 through 2000: Blood specimens were collected among women during the first three months postpartum and interviews conducted
- *Dependent variables*
  - RBC folate analysis: Measured using the Bio-Rad Laboratories Quantaphase II Folate/Vitamin B_{12} Radioassay kit
  - Serum folate analysis: Same method as above
- *Independent variables:* Mandatory folic acid fortification of enriched grain products by January, 1998
- *Control variables:*
  - Medical history
  - Periconceptional exposures including folic acid supplements (three months before conception to three months post-conception): women who took folic acid at three months post-conception were defined as "prenatal vitamin users."

Description of Actual Data Sample:

- *Initial N:* Women who were controls in a population-based case-control NTD study from 1995 through 2000.
- *Attrition:* After application of exclusion criteria, 193 women tested were analyzed in the study
- *Age:* Productive age
- *Ethnicity*: Predominantly Mexican-American
- *Other relevant demographics:* Half of the tested women had annual family incomes below $15,000 and less than 12 years of education
- *Anthropometrics:* Not applicable
- *Location:* 14 Texas-Mexico border counties, US.

Summary of Results:

- About half of the women were born in Mexico
- About half had annual family incomes below $15,000 and less than 12 years of education
- Among 193 women, 51 were for 1996, 27 for 1997, 44 for 1998 and 48 for 1999
- From 1996 through 1999, the median serum folate concentration increased modestly:
  - In 1996, the median serum folate concentration was 8.5ng/ml
  - In 1999, the median serum folate concentration was 12.4ng/ml (46% higher)
  - In 1996, the median RBC folate level was 272ng/ml, in 1999 the level was 393ng/ml (44% higher)
- The median RBC folate concentration in women without prenatal vitamin users was 254ng/ml in 1996 and 378ng/ml in 1999 (49% increase).

Author Conclusion:

The food fortification may be affecting folate levels among populations with economic and cultural barriers to consuming fortified foods.

Reviewer Comments:

- *More data and time were needed to assess the impact of food fortification on NTD rates on the border*
- *Women in the study were representative of the border population as a whole.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	???
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	???
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	No

2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	N/A
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	???
4.1.	Were follow-up methods described and the same for all groups?	N/A
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	No
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes

5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	???
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	???
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	No
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	N/A
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	N/A
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	No
8.1.	Were statistical analyses adequately described and the results reported appropriately?	No

8.2.	Were correct statistical tests used and assumptions of test not violated?	No
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	No
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
8.6.	Was clinical significance as well as statistical significance reported?	No
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes